

Remarks

Claims 29, 34 and 49 are pending for examination with claim 29 being the only independent claim and claim 34 being withdrawn. Claim 29 has been amended to clarify the claim language. Claim 34 has been amended to make its scope commensurate with that of claim 29. Claim 49 has been amended to make it an independent claim, thereby including the limitations of claim 29. New claim 50, directed to a method of use of the composition claimed in claim 49, has been added. Claim 50 is intended to be a counterpart of claim 34, but of a scope commensurate with claim 49. No new matter has been added.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claim 29 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description in the specification. Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Examiner has acknowledged that providing a representative number of compounds or a recitation of structural features common to the compounds having the effect of decreasing calcium influx of neuronal cells of the genus would be sufficient to provide an adequate written description. (Office Action at pages 5-6 and paragraph spanning pages 8 and 9) The Examiner concludes on page 9 of the Office Action that the specification does not satisfy either of these criteria.

The Examiner suggests that there are two reasons for rejecting Applicant's prior argument. First, there is no *per se* test for determining if the written description requirement has been met. Applicant agrees. Second, the Examiner asserts that “[t]he issue is whether the specification has provided a sufficient showing to demonstrate possession of the presently

claimed invention.” Applicant agrees with this second statement also, but respectfully disagrees with the conclusion reached by the Examiner.

The requirement for an adequate written description provides that the specification discloses the invention sufficiently such that the applicant conveys to one of ordinary skill in the art that the applicant was in possession of the invention as claimed. Vas-Cath v. Mahurkar, 35 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). Applicant in this case has done so. The term “compounds that decrease calcium influx of neuronal cells”, particularly in combination with the description of specific compounds provided in the specification, is more than adequate to convey to the skilled person that Applicant was in possession of the invention.

The claims recite compounds that decrease calcium influx of neuronal cells. Applicant has removed the requirement that the calcium influx is caused by aggregated β-amyloid (Aβ) protein degradation products in the amended claims, because compounds that decrease calcium influx of neuronal cells is an art-recognized class of molecule, and because the calcium influx need not be caused by aggregated β-amyloid (Aβ) protein degradation products to characterize the compounds now claimed. It appears that the wording of the claims as previously written obscured the nature of the compounds and therefore Applicant has amended the claims to clarify the invention.

Among the compounds provided in the specification having this function are non-NMDA channel antagonists. Non-NMDA channel antagonists are a class of compounds recognized in the art. Applicant further provided a description of a number of this class of compounds in the specification. Additional compounds described in the application, and also representative of this class of compounds, are MgCl₂, and decoy peptides.

Because compounds that decrease calcium influx of neuronal cells are recognized in the art, the person of skill in the art can readily envision, based on the description in the specification, the invention now claimed. As the Examiner acknowledged, the case law does not require that a description of the structure of compounds be provided. Instead, a representative

number of compounds can be provided in order to provide an adequate written description. Moreover, patent applications are written for persons of skill in the art, who are expected to have knowledge of the art. As noted above, one of ordinary skill in the art is very familiar with compounds that decrease calcium influx of neuronal cells. Therefore, the description in the specification in combination with the knowledge of the skilled person is sufficient to convey possession of the claimed invention to one of ordinary skill in the art.

The Examiner also stated that the claimed compounds that decrease calcium influx of neuronal cells caused by aggregated β -amyloid ($A\beta$) protein degradation products represent "a vague functional description which lacks any structural feature (e.g., core structure) common to the compounds that decrease calcium influx". (Office Action at page 8). The Examiner cites to the University of Rochester v. G.D. Searle & Co. case in support of this assertion. University of Rochester v. G.D. Searle & Co., 69 USPQ2d. 1886 (CAFC 2004). Applicant wishes to note the distinctions between the factual situations present in the Rochester case and the instant case. In Rochester, the patentee provided no information about the type or structure of compounds effective to inhibit COX-2 protein, nor was there any art-recognized class of compounds that could inhibit the protein. In contrast to the Rochester situation, in the instant case Applicant is claiming a combination of DAPH1 and compounds that decrease calcium influx of neuronal cells, which is an art-recognized class of compounds, and which were described in the specification. Thus, the holding of the Rochester case is not applicable to the present facts and the claimed invention.

The following references, available prior to the filing date of the instant application, describe that compounds that decrease calcium influx were well known in the art: Fernandez Pereira et al., Int J Dev Neurosci. 2000 Dec;18(8):773-80; Takahashi et al., Eur J Pharmacol. 2000 Nov 17;408(2):127-35; Katsura et al., Brain Res Mol Brain Res. 2000 Sep 15;80(2):132-41; and Yokoo, et al., Brain Res. 2000 Aug 4;873(1):149-54. These are merely a few of the many references describing compounds that decrease calcium influx known to one of ordinary skill in the art at the time that this application was filed.

The description required to convey to one of ordinary skill in the art that Applicant was in possession of the invention is analogous to the recitation of any known class of compounds (e.g., beta blockers, NSAIDs) or objects (e.g., fasteners, computers). The Examiner's view appears to be that those compounds that decrease calcium influx of neuronal cells require more description than those classes of items. Applicant respectfully disagrees, because the recitation provided is enough to convey to the person of skill in the art (who has a high level of skill in this art) that Applicant possessed the invention. Clearly Applicant has met the required burden.

Accordingly, Applicant's specification provides an adequate written description of claims 29 and 34 as presently amended. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph therefore is requested.

Rejoinder

Applicant thanks the Examiner for indicating that the Examiner would consider rejoinder of a method of use commensurate in scope with allowed claims.

To that end, Applicant has amended claim 34 to recite a method of use of the composition claimed in claim 29. To the extent that claim 29 is allowable, Applicant respectfully requests reconsideration of the method of use of claim 34. Applicant also has added new claim 50, which is a method of use of the composition of claim 49. As claim 49 was found to be allowable by the Examiner (if placed in independent form, which Applicant has now done), Applicant respectfully requests that the Examiner consider new claim 50 under the rules for rejoinder of method claims.

CONCLUSION

Applicant respectfully requests reconsideration of the claims in view of the amendments and reasoned statements made above. If the Examiner wishes to expedite the prosecution, or if the amendment is defective or unclear, then the Examiner is invited to telephone the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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